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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,766	06/27/2006	Allan L. Goldstein	2600-116	9880

6449 7590 09/10/2008

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
09/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/564,766	GOLDSTEIN, ALLAN L.	
	Examiner	Art Unit	
	DAVID LUKTON	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6 and 9-21* is/are pending in the application.

4a) Of the above claim(s) *10,12,13 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,9,11,14-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/6/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the response filed 6/6/08, various claims have been amended, and claims 19-21 added. Claims 1, 4-6, 9-21 are now pending. Claims 10, 12, 13, 18 remain withdrawn from consideration. Claims 1, 4-6, 9, 11, 14-17, 19-21 are examined in this Office action.

Applicants' arguments filed 6/6/08 have been considered and found persuasive in part. With the exception of the §103 rejection over Kleinman ('931), the previously imposed §103 rejections are withdrawn.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 9, 11, 14-17, 19-21 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have asserted that "damage" due to radiation exposure can be "inhibited" by

administering peptides that contain the LKKTET subsequence. However, there is no evidence that this is the case. Selecting compounds at random, and attributing randomly selected properties to them, tends to produce "unpredictable" results.

In response to the foregoing, applicants have argued that the compounds are not randomly selected. Perhaps this is true, and perhaps not; but the list produced by applicants could just as easily have been produced by a random selection process.

Next, applicants have argued that peptides which contain the LKKTET subsequence are effective to bind actin. This particular assertion will be left unchallenged at this point, but binding actin is quite different from "inhibiting radiation damage to tissue". Applicants have made no attempt to link the two. Why would the biochemist of ordinary skill come to believe that an actin-binding compound will inhibit tissue damage that results from radiation exposure? Perhaps applicants should be claiming a method of binding actin.

As indicated in the previous Office action, one or more claims are drawn to a method of "preventing" a given process, which method would not be enabled, **even if** applicants could demonstrate that radiation damage could be "inhibited" by administration of a LKKTET-containing peptide. In response to this, applicants have argued that the term "prevent" is no longer present. However, applicants assertion is not correct. For example, each of claims 15 and 16 recite the term at issue. Most puzzling of all is how applicants propose to achieve outright prevention of any and all tissue damage by administering the peptide **after** exposing the subject to radiation, as claim 15 suggests.

Even if the peptide could reverse 100% of the tissue damage induced by the radiation (a highly unlikely proposition to begin with), "prevention" would still not have been achieved.

Further to the foregoing, claim 9 recites the phrase "protect … stem cells". The meaning of the term "protect" overlaps that of "prevent", and the same arguments apply. It is suggested that, at the very least, applicants acknowledge the presence of the offending terms in claims 9, 15, and 16; otherwise there is little chance of advancing the dialog.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Accordingly, "undue experimentation" would be required to practice the claimed invention.

✧

Claims 9 and 15 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is drawn to a method of "protecting" stem cells via a process of "inhibiting" tissue damage. Suppose that the inhibition occurs to the extent of only 1%. How would applicants go about achieving "protection" in that case? It appears that there is a mismatch between "inhibiting" (on the one hand), and "protecting" (on the other hand). Similarly, in claim 15, there is a mismatch between "inhibiting" (on the one hand), and "preventing".

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1, 4-6, 9, 11, 14-17, 19-21 are rejected under 35 U.S.C. §103 as being unpatentable over Kleinman (US 2007/0111931).

As indicated previously, Kleinman discloses that thymosin *beta* 4 is effective to promote wound healing. One of ordinary skill would therefore expect that if tissue had been wounded by radiation (or some other cause) benefit would accrue by administering the thymosin.

In response, applicants have argued that the medical practitioner of ordinary skill would come to the conclusion that unless the wound has been caused by a surgical procedure,

laceration, a toxic chemical, a viral infection a bacterial infection or a burn, the wound will fail to heal in the presence of thymosin. However, no such reason is given by applicants for such a proposition. Moreover, the reference suggests (paragraph 0048) that the thymosin will be effective to treat tissue that has been damaged by irradiation.

The rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654